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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,757	01/03/2007	Emma Kvitnitsky	KVITNITSKY=1A	5965
1444 7590 02/26/2010 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER CHANDRAKUMAR, NIZAL S	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 02/26/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,757	<b>Applicant(s)</b> KVITNITSKY ET AL.	
	<b>Examiner</b> NIZAL S. CHANDRAKUMAR	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicants response filed 12/01/2009 is acknowledged.

#### **Claim Status:**

The claims being considered are pending claims 1-5 and claims 7-31 filed 12/01/2009.

Affidavit filed 08/31/2009 as well as the informal fax information provided by attorney Sheridan Neimark on 02/22/2010 were fully considered.

#### **Response to Applicants Remarks:**

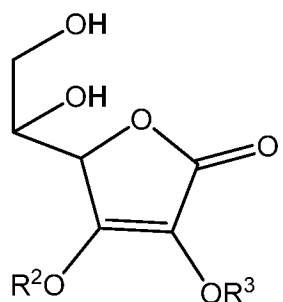
**Objection:** Previously presented objection (which was made in the context of Election/Restriction) is withdrawn in view of applicant's persuasive arguments.

The subject matter of elected group of invention is

Group 1, claim(s) 1-14, drawn to compounds and composition containing compounds of formula (I) wherein R3 and R4 are independently H.

Further, pursuant to the withdrawal of the restriction requirement (see page 2 of office action filed 09/01/2009), applicant is respectfully reminded that the subject matter being examined pertains to compounds and compositions of formula (I) wherein R4 and R3 are hydrogens. As such claims 1-5 and 7-31 are examined to the extent that they read on the formula

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R2 and R3 being the variables as instantly claimed.

***Claim Rejections - 35 USC § 103***

Upon further consideration, previously presented obviousness rejection is withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

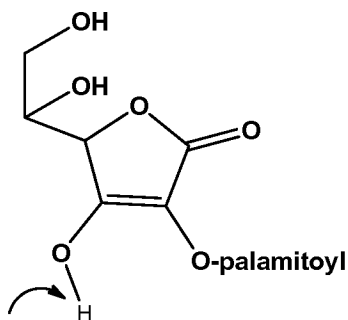
Previously presented rejection of claims 1-5 and claims 7-31 is maintained for reasons of record. Applicant's arguments as well as affidavit filed 08/31/2009 were fully considered but are not persuasive to overcome the rejection.

Applicants state that the declaration declares that those skilled in the art would be able to practice the invention as claimed based on what is disclosed in the present application coupled with common knowledge in the field, i.e.,

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'compounds of the formula defined in claim 1 of the present application may be obtained, using various technologies and procedures that have all been described in the literature and are known to any person skilled in the art.' These conclusions are supported by the experiments which are described in the attached Declaration.

In the previous office action, 112-1 scope of enablement (requirement of 'manner and process of making and using, in full, clear, concise, and exact terms) rejection rather than 112-1 written description (possession of invention at the time of application) rejection was presented because the specification is enabling for making



an obligatory intermediate to make the claimed compounds. Such compounds however, are well known in the prior art which teaches compounds wherein the above shown palmitoyl group has been replaced by (higher and lower) homologous groups. The instantly claimed compounds are salts of these compounds, that is, the H indicated by arrow in the above structure is replaced by the claimed  $R^2$  variables. As such, while guidance is present in the application for making compounds wherein  $R^2$  is H, there is no guidance in the specification for making compounds wherein  $R^2$  is as instantly claimed.

However, the issue in this case is whether the applicant had possession of the

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claimed compounds, *at the time of the instant application*. The affidavit pages 8-9 describes 'step v' that adequately provides for a method for converting the above shown structure (i.e., R2 = H) to the claimed compound (R2= Na, etc). This critical step 'step v' however is missing in the specification (see page16).

Thus the issue here is the time of possession of the invention. Based on the disclosure in the specification and the information in the declaration, Examiner respectfully questions the 'time of the possession of the invention' because

a) the declaration 8/31/2009 does not establish the date the 'step v' needed to make the R2 variables was recorded/completed

b) applicant's papers filed 03/23/2009, page 2 reads as follows:

Applicants hereby respectfully petition under 37 CFR §1.103(a) for a suspension of action by the PTO for three (3) months, for the following reasons. The applicants need additional time to carry out certain experiments which will produce additional experimental data showing both a complete process for the preparation of compounds of the present application, as well as significant enhancement for the efficacy of such compounds over the closest compounds disclosed in the prior art; and, in particular, the ascorbic acid derivatives of the present invention have better physical and chemical properties and are significantly more stable than those disclosed in the prior art, and to provide such data in the Declaration under 37 CFR §1.132.

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Given that the 'metes and bounds' of the invention is based on the R2 groups of the instant compounds, the question is: whether the above-mentioned 'step v' used for making these 'novel' R2 groups, was completed before the filing date of the instant application?

Previously presented rejection with respect to 'use aspect' of the enablement requirement is maintained for reasons of record. As previously indicated, the use of ascorbic acid compounds in cosmetic, dermatological and nutraceutical applications as well as in the treatment of cutaneous cancer and photo damaged skin can be acknowledged. Affidavit filed is fully considered but is not persuasive to overcome the rejection of claims 16-18. One of skilled in the art would not anticipate that mere enhanced stability to impart biological properties for the treatment of any and all cancer and immune system disorders.

Claims 1-5 and claims 7-31 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/  
Examiner, Art Unit 1625

/D. Margaret Seaman/  
Primary Examiner, Art Unit 1625